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14. ABSTRACT

Many service members exposed to combat and operational stressors develop posttraumatic stress disorder (PTSD). Evidence-based interventions for treating PTSD, however, were not developed for military trauma and thus may be suboptimal for this population. This study compares Adaptive Disclosure, an intervention for Marines and Sailors with PTSD stemming from deployment experiences, to an empirically supported PTSD treatment. The report details the fifth year of work on this trial, in which we continued recruitment. The Boston team has principally been involved in conducting pre- and post-treatment psychosocial assessments that will be used to determine treatment efficacy.

15. SUBJECT TERMS

Active-duty, Marine Corps, Posttraumatic stress disorder, Cognitive Therapy

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Supporting Data	n/a

INTRODUCTION:

More than 2 million U.S. troops have served in the wars in Afghanistan and Iraq. Findings from epidemiologic studies of infantry troops in the early stages of the wars suggest that 10-18% of combat troops experience deployment-related psychological health problems, such as posttraumatic stress disorder (PTSD; e.g., Hoge et al., 2004; see Litz & Schlenger, 2009). Once service members and new Veterans develop sustained mental health problems related to combat and operational stress, many are at risk to remain chronic across the lifespan (e.g., Kessler et al., 1995; Kulka et al., 1990; Prigerson et al., 2001). Thus, primary and secondary prevention of PTSD is a critical challenge for the military and the VA (e.g., Litz & Bryant, 2009). We have developed a novel intervention, Adaptive Disclosure (AD), to address these needs. AD is a hybrid and extension of evidence-informed cognitive-behavioral therapy strategies packaged and sequenced to target the three high base-rate combat and operational traumas, namely, life-threat trauma, loss (principally traumatic loss), and experiences that produce inner moral conflict (Steenkamp et al., 2011). AD employs a Prolonged Exposure (PE) strategy (imaginal emotional processing of an event) and cognitive-therapy-based techniques used in Cognitive Processing Therapy (CPT), but also includes gestalt-therapy techniques designed to target loss and moral injury. In our open pilot trial, we demonstrated treatment acceptability among Marines and large reductions in PTSD and comorbid symptoms. The primary objective of the current randomized control non-inferiority trial is to determine whether AD is as least as effective as CPT, cognitive only version (CPT-C), in terms of its impact on deployment-related psychological health problems (specifically PTSD and depression) and functioning.

BODY:

Preparatory Phase (Months 1 - 6)

- Regulatory Review and IRB Approval (Months 1-6): All necessary IRB approvals have been obtained.
- Database Development (Months 4-6): A study database has been established.
- Hire and Train Study Personnel (Months 1-6): All necessary hiring, credentialing, training, and certification of study personnel is complete.
- Miscellaneous Preparatory Tasks (Months 1-6): All miscellaneous preparatory activities have been successfully completed.

Patient Recruitment & Enrollment (Months 25 – 58): This report has been revised to acknowledge that recruitment began in 2013 after extensive unanticipated legal and regulatory hurdles. We have had two approved extensions (adding a fifth year and a sixth year) and are in final negotiations to get a plus-up for year six. Through month 58, we have recruited 106 of the 266 planned participants. Because we no longer qualify for supplemental funds to the original award, we have applied for continuation funding to complete the trial. Through year five, the Boston site has conducted 124 pre-treatment assessments, and 62 post-treatment assessments (186 total). No adverse events occurred. These assessments were audio-recorded and a random subsample was sent to Dr. Matt Gray, University of Wyoming, for adherence monitoring. We provided ongoing therapy supervision to study therapists. We also received and stored deidentified data from San Diego.

<u>Follow-Up Data Collection & Patient Closeout (Months 37 - 70)</u>: Data collection is ongoing. To date, the Boston site conducted 124 pre-treatment assessments, and 62 post-treatment assessments (186 total). No adverse events have occurred. These assessments are audio-recorded

and a random subsample has been sent to Dr. Matt Gray, University of Wyoming, for adherence monitoring. We are providing ongoing therapy supervision to study therapists. We are receiving and storing de-identified data from San Diego. We created a study database and are entering data for the currently enrolled participants.

Data Analysis & Report Writing, Dissemination (Months 43-70): N/A

KEY RESEARCH ACCOMPLISHMENTS: We are currently enrolling participants in this protocol and are entering the data into the study database.

REPORTABLE OUTCOMES: None in this period.

CONCLUSION: The Boston site is actively assessing study participants and entering data.

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APPENDICES: None